UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

JACOB BRICKMAN,

Plaintiff,

v. Civil Action No.: _____

EXACTECH, INC.,

Defendant.

COMPLAINT AND JURY DEMAND

NOW COMES Plaintiff JACOB BRICKMAN ("Plaintiff") by and through his undersigned attorneys, and brings this action against EXACTECH, INC. ("EXACTECH" or "Defendant"), for personal injuries suffered as a proximate result of the implantation of an Optetrak Comprehensive Total Knee System (hereafter, "Optetrak Device") and alleges as follows:

NATURE OF THE ACTION

1. This is an action for damages relating to Defendant's development, designing, testing, assembling, manufacturing, packaging, monitoring, labeling, preparing, distribution, marketing, supplying, storage, and/or selling of the Optetrak

Device. The Optetrak Devices, as referred to in this Complaint, include the Optetrak Device and the Optetrak Logic Comprehensive Knee System.

2. Thousands of patients, like Plaintiff JACOB BRICKMAN, have been, and/or will be, required to undergo extensive revision surgery to remove and replace defective Optetrak Devices due to a recent recall of these devices in which the Defendant has admitted to failing to properly package the polyethylene insert, a necessary component of the Optetrak Devices.

3. As a result of Defendant's failure to properly package the Optetrak Device prior to distribution, the polyethylene liner prematurely degraded and Plaintiff required revision surgeries due to severe pain, swelling, and instability in the knee and leg. These injuries were caused by early and preventable wear of the polyethylene insert and resulting component loosening and/or other failures causing serious complications including tissue damage, osteolysis, permanent bone loss and other injuries.

4. Recipients of Optetrak Devices, like the Plaintiff, have been required to undergo revision surgeries well before the estimated life expectancy of a knee implant and at a much higher rate than should reasonably be expected for devices of

this kind and have suffered pain and disability leading up to and subsequent to the revision surgery.

5. Despite knowledge that the Optetrak Devices were defective and resulted in premature failures and accompanying complications, Defendant only first issued a nationwide recall on February 7, 2022 advising the public that "most of our inserts since 2004 were packaged in out-of-specification … vacuum bags that are oxygen resistant but do not contain a secondary barrier layer containing ethylene vinyl alcohol (EVOH) that further augments oxygen resistance."

6. As a direct and proximate result of the defective nature of Defendant's Optetrak Device surgically implanted in Plaintiff which necessitated premature removal, Plaintiff suffered and will continue to suffer serious personal injuries, including pain, impaired mobility, rehabilitation, medical care, loss of enjoyment of life, and other medical and non-medical sequalae.

7. Plaintiff brings this action for personal injuries suffered as a proximate result of failure of the Optetrak Device. Plaintiff accordingly seeks compensatory and punitive damages, and all other available remedies provided to Plaintiff under the law as a result of injuries JACOB BRICKMAN sustained due to the Defendant's negligent, reckless and wrongful conduct.

PARTIES

8. Plaintiff JACOB BRICKMAN is a resident and citizen of Warminster, County of Bucks, Pennsylvania.

9. Defendant EXACTECH, INC. is a Florida corporation with its principal place of business located at 2320 NW 66th Court, Gainesville, Florida 32653. It can be served c/o its Registered Agent Corporation Service Company, 2595 Interstate Drive, Suite 103, Harrisburg, PA 17110.

10. Defendant EXACTECH, INC. develops, manufactures, packages, stores, distributes, markets, and sells orthopedic implant devices, including Optetrak Devices and related surgical instrumentation throughout the United States, including in and throughout the United States and the State of Pennsylvania.

11. Defendant EXACTECH, INC. manufactured the Optetrak Device implanted in Plaintiff JACOB BRICKMAN.

12. At all times relevant to this action, Defendant EXACTECH, INC. tested, studied, researched, designed, formulated, manufactured, inspected, labeled, packaged, promoted, advertised, marketed, distributed, and/or sold Optetrak Devices in interstate commerce and throughout the State of Pennsylvania and generated substantial revenue as a result.

JURISDICTION AND VENUE

13. This Court has jurisdiction over this action pursuant to 28 U.S.C § 1332, because the amount in controversy exceeds Seventy-Five Thousand Dollars ($75,000.00), exclusive of interest and costs, and because there is complete diversity of citizenship between the Plaintiff and Defendant.

14. The Court has personal jurisdiction over Defendant because at all relevant times it engaged in substantial business activities in the State of Pennsylvania. At all relevant times, Defendant transacted, solicited, and conducted business in Pennsylvania through its employees, agents, and/or sales representatives, and derived substantial revenue from such business in Pennsylvania.

15. Venue is proper in this judicial district pursuant to 28 U.S.C § 1391 because Plaintiff is a citizen and resident of Bucks County, Pennsylvania, and because a substantial part of the events or omissions giving rise to the claim occurred within this judicial district.

FACTUAL BACKGROUND

16. At all times material hereto, Defendant designed, developed tested, assembled, selected, manufactured, packaged, labeled, prepared, distributed,

marketed, supplied, warranted, and/or sold the Optetrak Devices to hospitals and physicians in many states, including Pennsylvania.

17. Defendant obtained 510(k) clearance from the Food and Drug Administration ("FDA") for various Optetrak Devices and components between 1994 and 2017, including marketing under the names: Optetrak, Optetrak Logic and Truliant.

18. 510(k) clearance is distinct from the FDA's pre-market approval ("PMA") process in that clearance does not require clinically controlled trials and FDA confirmation of safety and effectiveness, and as such the manufacturer retains all liability for the assertions of safety and effectiveness.

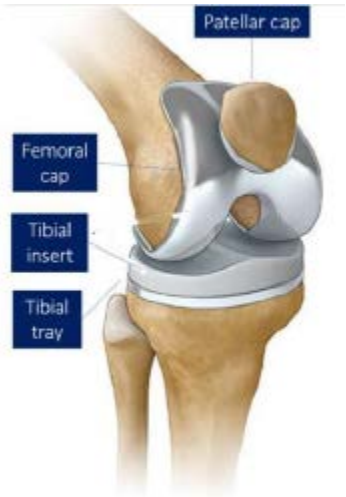
19. 510(k) clearance is premised upon the manufacturer's representations to the FDA under section 510(k) of the Medical Device Amendments of 1976 to the Food Device Cosmetic Act (MDA) of its intent to market a device.

20. All the component parts comprising Plaintiff's Optetrak Device were cleared for marketing by the FDA pursuant to the 510(k) process or were marketed without receiving either 510(k) clearance or PMA approval by the FDA.

21. The Optetrak Device is classified as a knee joint patellofemorotibial polymer/ metal /polymer semi-constrained cemented prosthesis. It features a mix of polyethylene and metal-based components.

22. According to the Defendant, the Optetrak Device "introduces novel implants and instruments to make the total knee procedure, easier, faster and more consistent, improving patient satisfaction for a more diverse population requiring total knee replacements."

23. The Optetrak Device is comprised of the following parts: a patellar cap, femoral cap, tibial insert, and tibial tray, as shown above.



24. The patellar cap and tibial insert are made of ultra-high molecular weight polyethylene ("UHMWPE").

25. Defendant touted the Optetrak Device as being first-in-class in its product brochures.

26. In its marketing materials, the Defendant promised that Optetrak Devices had excellent long-term clinical outcomes and that "surgeons and patients can have every confidence in the performance and longevity of the Optetrak knee system."

27. Defendant promoted its Optetrak Devices as systems with nearly three decades of clinical success and proven outcomes for patients around the world because of an improved articular design resulting in low polyethylene stresses.

28. However, Optetrak Devices have performed poorly when compared to their competitors. For example, the Australian Orthopaedic Association, a preeminent, internationally recognized orthopedic implant registry, has identified the Optetrak Device as an implant with a higher than expected rate of revision.

29. According to the 2020 Australian National Joint Replacement Registry, the rate of revision for a total knee replacement utilizing an Optetrak tibial component with a Optetrak-CR femoral component was 8.5% at ten years and 10.2%

at ten years when implanted with a Opetrak-PS femoral component, which far exceeds international guidelines for accepted revision rates.

30. Per the recommendations established by the International Benchmarking Working Group and applied by the Australian Orthopaedic Association, the Optetrak Devices do not qualify for a "superiority benchmark" or even a "non-inferiority benchmark."

31. At all relevant times, Defendant has been aware of a high rate of early failures associated with the Optetrak Devices.

32. Upon information and belief, by the beginning of 2011, Defendant had clinical evidence that Optetrak Devices were failing at a rate higher than promoted. Reports in the Manufacturer and User Facility Device Experience (MAUDE) indicate instances of revision due to "loose tibial component", "aseptic loosening", "pain and visible loosening", "polyethylene deformation", "polyethylene worn", and "pain, limited mobility, knee swelling and sensitivity" due to "loose" joint.

33. Prior to Plaintiffs' knee implants with Optetrak Devices in 2011, complaints continued to be reported to Defendant and the FDA. Examples include revision for "tibial loosening" just two years postoperatively, "revision due to tibial loosening", "during revision, the tibial component was found to be loose and easily

removed", "revision of knee component due to loosening", "revision due to pain and loosening."

34. The general practice in orthopedic implant surgeries generally, and with Exactech implants specifically, is for the authorized representative and agent, hereinafter "the sales rep", to be present at the time of surgery to provide technical knowledge, tools, and in many cases implant components to the surgeon. This practice is utilized in both implant or "index" and any revision surgeries.

35. Based upon the industry norms and the policies of Defendant, Exactech sales reps were present during surgeries, observing many instances of premature failures of the Optetrak Devices, with plain evidence upon revision of polyethylene debris that needed to be removed, a/k/a "debrided", visible bone loss or osteolysis and plainly loose components that were easy to remove due to fixation failures. As is the norm of the industry, it is believed that Defendant's sales reps would take explanted Optetrak Device components from the surgeon to return to the company for inspection and analysis.

36. The Exactech sales reps were under a duty to report findings of premature failure, defect, complaints, revisions, and other instances providing notice of adverse events to the engineering and medical departments of Exactech, which

were under a duty to then do an investigation, analyze the removed component when available, also known as "retrieval analysis," and to honestly and thoroughly report such findings to the FDA and the surgeons.

37. Despite Defendant's knowledge of early onset failures of Optetrak Devices, Defendant continued to manufacture, promote, and distribute Optetrak Devices without alerting surgeons or patients of the potential increased risks of early onset failures of the Optetrak Devices.

38. Defendant never changed the labeling, marketing materials, or product inserts to adequately and accurately warn patients or physicians of the associated increased risks of early failure due to adverse reaction to debris, increased wear debris associated with the tibial insert, and risks associated with moderately cross-linked polyethylene.

39. It was not until August 30, 2021 that the Defendant took some action and issued a recall of Optetrak all-polyethylene tibial components, including the OPTETRAK polyethylene CC Tibial Components; OPTETRAK All-polyethylene CR Tibial Components; OPTETRAK All-polyethylene CR Tibial Sloped Components; OPTERAK All-polyethylene PS Tibial Components; OPTETRAK HI-FLEX PS Polyethylene Tibial Components; OPTETRAK Logic All-

polyethylene CR Tibial Components; OPTETRAK Logic All-polyethylene CRC Tibial Components; OPTETRAK Logic All-polyethylene PSC Tibial Components; OPTETRAK Logic Modular PS Tibial Components; OPTETRAK Logic RBK PS Tibial Components; TRULIANT CR Tibial Inserts; TRULIANT CRC Tibial Inserts; TRULIANT PS Tibial Inserts; and TRULIANT PSC Tibial Inserts.

40. In issuing the August 2021 recall, Defendant stated "inserts were packaged in vacuum bags that lacked an additional oxygen barrier layer." *See* "Class 2 Device Recall OPTETRAK Comprehensive Knee System", FDA, *available at* https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRes/res.cfm?ID=189266 (last visited June 6, 2022).

41. According to the FDA website, "Exactech began notification to distributors and sales representatives on about 08/30/2021 via letter titled "URGENT MEDICAL DEVICE RECALL." Actions taken by Exactech included removing all Knee and Ankle UHMWPE products labeled with an 8-year shelf life and not packaged in EVOH/Nylon bags, to "be performed in a phased approach over the next 12 months. Phase 1 includes immediately return all knee and ankle UHMWPE devices labeled with an 8-year shelf life that will be 5 years old or older by 08/31/2022 not packaged in EVOH/Nylon bags. Phase 2 includes, between

05/31/2022 to 08/31/2022, returning all remaining knee and ankle UHMWPE devices labeled with an 8-year shelf life not packaged in EVOH/Nylon bags." *Id.*

42. Despite initial communications with distributors and sales representatives, Defendant did not issue notice, warning, or communications to surgeons who had implanted Optetrak Devices with recalled polyethylene components or to patients who had received Optetrak Devices with a recalled polyethylene component about the risks, defect and/or recall until months later, in February 2022.

43. On February 7, 2022, Defendant issued an "Urgent Medical Device Correction" in which it informed health care professionals that:

> After extensive testing, we have confirmed that most of our inserts manufactured since 2004 were packaged in out-of-specification (referred to hereafter as "nonconforming") vacuum bags that are oxygen resistant but do not contain a secondary barrier layer containing ethylene vinyl alcohol (EVOH) that further augments oxygen resistance. **The use of these non-conforming bags may enable increased oxygen diffusion to the UHMWPE (ultra-high molecular weight polyethylene) insert, resulting in increased oxidation of the material relative to inserts packaged with the specified additional oxygen barrier layer. Over time, oxidation can severely degrade the mechanical properties of conventional UHMWPE, which, in conjunction with other surgical factors, can lead to both accelerated wear debris production and bone loss, and/or component fatigue cracking/fracture, all leading to corrective revision surgery.**

(Emphasis in original).

44. On or about April 6, 2022, Exactech removed the aforementioned February 7, 2022 letter from its website and replaced it with a version dated April 7, 2022 that now states in relevant part:

> After extensive testing, we have confirmed **that approximately 80% of our inserts manufactured since 2004 were packaged in out-of-specification (referred to hereafter as "non-conforming") vacuum bags** that are oxygen resistant but do not contain a secondary barrier layer containing ethylene vinyl alcohol (EVOH) that further augments oxygen resistance.

(Emphasis added). *See* Exactech Urgent Medical Device Correction Letter to Exactech Knee and Ankle Surgeons, Hospitals, Health Care Professionals, Apr. 7, 2022, *available at* https://www.exac.com/wp-content/uploads/2022/04/Exactech-DHCP-letter.4.6.2022.pdf (last accessed April 29, 2022). The updated letter also recalls the Optetrak Unicondylar Tibial Components; new Optetrak Total Knee Replacement System Components; and clarifies that 143,484 non-confirming inserts have been implanted in the US since 2004.

45. The "Urgent Medical Device Correction" further states that Exactech was expanding the recall to include all knee arthroplasty polyethylene inserts packed in nonconforming bags, regardless of label or shelf life. The components subject to

the recall now included: OPTETRAK®: All-polyethylene CR Tibial Components, All-polyethylene PS Tibial Components, CR Tibial Inserts, CR Slope Tibial Inserts, PS Tibial Inserts, HI-FLEX® PS Tibial Inserts; OPTETRACK Logic®: CR Tibial Inserts, CR Slope Tibial Inserts, CRC Tibial Inserts, PS Tibial Inserts, PSC Tibial Inserts, CC Tibial Inserts; and TRULIANT®: CR Tibial Inserts, CR Slope Tibial Inserts, CRC Tibial Inserts, PS Tibial Inserts, PSC Tibial Inserts, and OPTETRAK® Unicondylar Tibial Components. *Id.*

46. Defendant further acknowledged the original Optetrak knee system has shown statistically significant higher overall revision rates compared to other total knee arthroplasties in the Australian, United Kingdom and New Zealand joint registries. *Id.*

47. Specifically, reasons for revision associated with polyethylene wear, including loosening, lysis, and pain, were increased three-to seven-fold with the Optetrak total knee replacement combination of the Optetrak-PS/Optetrak according to the 2021 Australian National Joint Replacement Registry with revision diagnoses related to accelerated polyethylene wear possibly related to the non-conforming packaging. *Id.*

48. Implanting surgeons were advised in February 2022 to contact patients previously implanted with recalled components and to schedule an evaluation if the patient is experiencing any new or worsening knee swelling, pain while walking, inability to bear weight, grinding or other noise, instability, or any new symptoms of clicking in the knee. *Id.*

49. Furthermore, Defendant advised surgeons that revision surgery should be considered for patients who exhibit premature polyethylene wear. *Id.*

50. Based on Defendant's own representations, since 2004, Defendant manufactured, promoted, and distributed the Optetrak Device without ensuring the polyethylene components were properly packaged to prevent or minimize oxidation. At no point until August 2021 did Defendant first modify the packaging in an effort to address this defect.

51. In approximately 2017 – 2018, Exactech, Inc. was in the process of being acquired by the Private Equity Group TPG Capital which in February 2018 successfully completed a merger agreement. As a result, TPG acquired all of the issued and outstanding common stock of Exactech. In connection with the transaction, Exactech's founders, CEO and certain other management shareholders exchanged a portion of their shares in the transaction, for new equity securities in

the post-closing ownership of the Company. *See Exactech Announces Completion of Merger with TPG Capital* (Feb. 14, 2018) *available at* https://www.exac.com/exactech-announces-completion-of-merger-with-tpg-capital/ (last visited June 6, 2022).

52. Disclosure of knowledge of the improper packaging, excessive premature failure rates, and or defects of the polyethylene components of Defendant's knee, hips, and ankle devices could have harmed this transaction.

53. At all times relevant to this action, Defendant was aware of the Optetrak Devices' propensity to undergo substantial early polyethylene wear consisting of the degradation and breakdown of the plastic chemicals causing toxicity to the tissue and bone and component loosening and/or other failure causing serious complications including tissue damage, osteolysis, and other injuries as well as the need for revision surgery and its attendant complications in patients.

54. At all times relevant to this action, Defendant failed to acknowledge the manufacturing defects in the Optetrak Devices due to poor and inadequate quality assurance procedures and due to a wanton and reckless disregard for public safety. Defendant also failed to implement or utilize adequate safeguards, tests, inspections,

validation, monitoring and quality assessments to ensure the safety of the Optetrak Devices.

55. At the time the Optetrak Devices were manufactured and sold to patients, including Plaintiff, the devices were defectively manufactured and unreasonably dangerous, and did not conform to federal regulations because the devices subjected patients to unreasonable risks of injury.

56. At all times relevant to this action, Defendant's inadequate manufacturing processes also led to material flaws in the quality systems at its manufacturing, packaging, storage, and distribution facilities.

57. During the course of manufacturing and distributing the Optetrak Devices, Defendant failed in several ways, including, without limitation, by:

a. failing to conduct adequate mechanical testing, including oxygen-resistance or other wear testing for the components, subassemblies, and/or finished Optetrak Devices;

b. failing to test an adequate number of sample devices on an ongoing basis;

c. failing to take adequate steps to specifically identify failure modes with clarity and to suggest methods to monitor, avoid, and/or prevent further failures;

d. failing to identify and/or note the significance of any testing that resulted in failure of the Optetrak Devices;

e. failing to take corrective actions to eliminate or minimize further failures of the Optetrak Devices;

f. failing to adequately explain packaging specifications for the components, subassemblies, and/or finished Optetrak Devices;

g. failing to perform adequate quality control before the components, subassemblies, and/or finished Optetrak Devices were distributed;

h. failing to properly address reports from its sales representatives who reported their observations while attending revision surgeries where evidence of polyethylene debris and osteolysis was apparent and noted by the surgeons and the sales representatives themselves;

i. failing to timely implement corrective action and investigations to understand the root cause of these failures while continuing to sell the

components knowing they would be implanted into the bodies of thousands of people; and

j. becoming aware of the potential cause or causes but unreasonably avoiding informing patients and surgeons and delaying the ability to minimize damages as the devices continued to degrade and do damage in the patients' bodies.

58. On or before the date of Plaintiff's initial knee replacement surgery, Defendant knew or should have known the Optetrak Device was failing and causing serious complications after implantation in patients. Such complications included, but were not limited to, catastrophic polyethylene wear including the deposition of plastic particulate wear debris throughout the knee, a high rate of component loosening, and overall early system failure resulting in tissue destruction, osteolysis, and other injuries causing severe pain, swelling, instability and dysfunction in the knee and leg necessitating revision surgery.

59. Defendant as a manufacturer of orthopedic devices knew that each surgery, especially a revision surgery, is always more complicated than an initial knee replacement surgery and is fraught with serious risks of infection, anesthesia errors, dislocations and other serious complications that should be avoided.

60. Defendant, however, ignored reports of early failures of its Optetrak Devices and failed to promptly investigate the cause of such failures or issue any communications or warnings to orthopedic surgeons and other healthcare providers.

61. Before the date of Plaintiff's initial knee replacement surgery, Defendant knew or should have known that the Optetrak Device was defective and unreasonably dangerous to patients, that the product had an unacceptable failure and complication rate, and that the product had a greater propensity to undergo substantial early polyethylene wear, component loosening and/or other failure causing serious complications including tissue damage, osteolysis, and other injuries as well as the need for revision surgery in patients.

JACOB BRICKMAN'S IMPLANTS AND REVISION SURGERIES

62. In 2011, Plaintiff JACOB BRICKMAN underwent bilateral total knee replacement surgery and was implanted with an Optetrak Device in each knee.

63. Plaintiff experienced extreme pain and discomfort in both knees which limited his activities of daily living and his quality of life.

64. Plaintiff JACOB BRICKMAN underwent revision surgery on his left knee on June 7, 2018, and the polyethylene liner and the entire femur and tibial components were revised. Orthopedic surgeon Dr. David V. Craft's operative notes

in part that "[t]here was gross failure of the medial polyethylene as well as significant erosion of the patella polyethylene. Neither was salvageable. The polyethylene implant was loose on the patella and was removed with the oscillating saw. Unfortunately, there were diffuse caseous bone loss from particle debris and giant cell inflammation …. There was significant bone loss on both the posterior aspects of the medial and lateral femoral condyles."

65. On February 23, 2022, Plaintiff JACOB BRICKMAN underwent revision surgery on his right knee. Orthopedic surgeon Dr. Chad Krueger's operative notes report that "there was massive and gross soft tissue destruction and bony destruction within his right knee. The patella button was free-floating. The patella itself was quite mush and without any salvageable bone. The polyethylene was grossly worn and removed by hand ….Our attention was then turned to the tibia, which again had a large bony defects within the metaphysis and the end of the bone itself."

66. As a direct, proximate and legal consequence of the defective nature of the Optetrak Device as described herein, Plaintiff has suffered and continues to suffer permanent and debilitating injures and damages, including but not limited to, significant pain and discomfort; gait impairment; poor balance; difficulty walking;

component part loosening; soft tissue damage; bone loss; and other injuries presently undiagnosed, which all require ongoing medical care.

67. As a further direct, proximate and legal consequence of the defective nature of the Optetrak Device, Plaintiff has sustained and will sustain future damages, including but not limited to cost of medical care; rehabilitation; home health care; loss of earning capacity; mental and emotional distress and pain and suffering.

CAUSES OF ACTION

FIRST CAUSE OF ACTION

STRICT LIABILITY – MANUFACTURING DEFECT

68. Plaintiff hereby incorporates by reference the facts alleged in paragraphs 1-67 of this Complaint as if fully set forth herein, and further alleges as follows:

69. Prior to Plaintiff's initial knee surgery, and at all times relevant this action, Defendant tested, studied, researched, designed, formulated, manufactured, inspected, labeled, packaged, promoted, advertised, marketed, distributed, and/or sold the Optetrak Devices for implantation into consumers, such as Plaintiff, by orthopedic surgeons in the United States.

70. The Defendant had a duty to manufacture the Optetrak Devices in a manner that prevents unreasonable risk of harm or injury to users and patients, including Plaintiff.

71. The Defendant had a duty to distribute, market, and/or sell the Optetrak Devices without manufacturing and related packaging defects to prevent an unreasonable risk of harm or injury to users and patients, including Plaintiff.

72. The Optetrak Devices manufactured by the Defendant were not reasonably safe for their expected, intended, and/or foreseeable uses, functions and purposes.

73. The Optetrak Devices were not reasonably safe as manufactured, packaged, distributed, marketed and/or sold by the Defendant.

74. The defects in manufacture of the Optetrak Device were a substantial factor in causing Plaintiff's injuries.

75. At all times herein mentioned, the Defendant tested, studied, researched, designed, formulated, manufactured, inspected, labeled, packaged, promoted, advertised, marketed, distributed, and/or sold Optetrak Devices, which were implanted in Plaintiff, such that they were dangerous, unsafe, and defective in manufacture. The defects in manufacture include but are not limited to:

a. failure to package the polyethylene components of the Optetrak Devices in vacuum bags that contain a secondary barrier layer containing ethylene vinyl alcohol (EVOH) as to prevent the components from undergoing increased oxidation and causing patients to experience substantial early polyethylene wear, component loosening and/or other failure causing serious complications including tissue damage, osteolysis, and other injuries as well as the need for revision surgery;

b. the materials used to package the Optetrak Devices were of an inferior grade or quality;

c. that the Optetrak Devices as manufactured differed from Defendant's intended specifications;

d. that Defendant failed to measure and/or test an adequate number of samples of Optetrak Devices on an ongoing basis;

e. that Defendant failed to take corrective actions to eliminate or minimize further failures of the Optetrak Devices;

f. that Defendant failed to perform adequate quality control or other such testing on the polyethylene inserts used in the Optetrak Devices to

ensure they complied with required specifications and were not prematurely degrading while stored;

g. failing to select appropriate third-parties to package the polyethylene inserts used in the Optetrak Devices;

h. failing to properly supervise and monitor the packaging of the polyethylene inserts used in the Optetrak Devices;

i. that Defendant failed to exercise sufficient quality control to ensure the polyethylene inserts in the Optetrak Devices were safe for implantation in users and patients and would not degrade abnormally under average and regular use; and

j. that Defendant violated applicable state and federal laws and regulations; and in all other ways.

76. Defendant knew or reasonably should have known and been aware that the Optetrak Devices were defectively manufactured.

77. The manufacturing defects in the Optetrak Devices existed when the device left the Defendant's control.

78. Plaintiff's physician implanted the Optetrak Devices in the manner intended and recommended to be used, making such use reasonably foreseeable to Defendant.

79. The Optetrak Devices as tested, studied, researched, designed, formulated, manufactured, inspected, labeled, packaged, promoted, advertised, marketed, distributed, and/or sold by Defendant reached Plaintiff without substantial change in their condition.

80. As alleged herein, Defendant knew or had reason to know that the Optetrak Devices caused an increased risk of harm to the Plaintiff and other consumers due to their propensity to undergo substantial early polyethylene wear, component loosening, and/or other failure causing serious complications including tissue damage, osteolysis, and other injuries as well as the need for revision surgery in patients.

81. The manufacturing defects of the Optetrak Devices presented an unreasonable risk of harm to users and patients exposed to their danger, including Plaintiff, when used and operated for the purposes intended by Defendant.

82. The manufacturing defects of the Optetrak Devices presented an unreasonable risk of harm to users and patients exposed to their danger, including

Plaintiff, when they were used and operated in a manner that was foreseeable to Defendant.

83. Plaintiff could not, by the exercise of reasonable care, have discovered the manufacturing defect and perceived its dangers or avoided injury.

84. The Defendant is strictly liable for the defective manufacture of the Optetrak Devices; the distribution, marketing, and/or sale of the defectively manufactured Optetrak Devices; and the injuries sustained by Plaintiff.

85. By reason of the foregoing acts, omissions and conduct committed by the Defendant, Plaintiff was caused to sustain serious personal injuries, conscious pain and suffering, physical disability, mental anguish, emotional distress, fear, loss of enjoyment of life, medical expenses, and financial losses.

86. By reason of the foregoing acts, omissions and conduct committed by Defendant, Plaintiff was caused to sustain serious personal injuries, conscious pain and suffering, and physical disability that will require continued and additional medical treatment.

87. As a direct, proximate and legal consequence of the defective nature of the Optetrak Devices as described herein Plaintiff JACOB BRICKMAN has suffered and continues to suffer permanent and debilitating injures and damages, including

but not limited to, significant pain and discomfort; gait impairment; poor balance; difficulty walking; component part loosening; soft tissue damage; bone loss; and other injuries presently undiagnosed, which all require ongoing medical care.

88. As a further direct, proximate and legal consequence of the defective nature of the Optetrak Devices, Plaintiff has sustained and will sustain future damages, including but not limited to cost of medical care; rehabilitation; home health care; loss of earning capacity; mental and emotional distress; and pain and suffering.

89. Defendant acted intentionally, recklessly, and wantonly, without regard for Plaintiff' rights beyond all standards of decency, entitling Plaintiff to recover punitive damages.

WHEREFORE, Plaintiff demands judgment against Defendant for compensatory and punitive damages, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems proper.

SECOND CAUSE OF ACTION

STRICT LIABILITY – DESIGN DEFECT

90. Plaintiff hereby incorporates by reference the facts alleged in paragraphs 1-67 of this Complaint as if fully set forth herein, and further alleges as follows:

91. Prior to Plaintiff's initial knee replacement surgeries, and at all times relevant this action, Defendant tested, studied, researched, designed, formulated, manufactured, inspected, labeled, packaged, promoted, advertised, marketed, distributed, and/or sold the Optetrak Devices for implantation into consumers, such as Plaintiff, by orthopedic surgeons in the United States.

92. Defendant had a duty to design and package the Optetrak Devices in a manner that did not present an unreasonable risk of harm or injury to users and patients exposed to their danger, including Plaintiff.

93. Defendant had a duty to distribute, market, and/or sell the Optetrak Devices with a design that did not present an unreasonable risk of harm or injury to users and patients exposed to their danger, including Plaintiff.

94. The design of the Optetrak Devices and their corresponding packaging is defective and not reasonably safe for their expected, intended, and/or foreseeable uses, functions, and purposes.

95. The Optetrak Devices and corresponding packaging are not reasonably safe as designed, distributed, marketed, delivered, and/or sold by Defendant.

96. The defective design of the Optetrak Devices and packaging received by Plaintiff's implanting surgeon were a substantial factor in causing Plaintiff' injuries.

97. At all times relevant to this action, the Defendant tested, studied, researched, designed, formulated, manufactured, inspected, labeled, packaged, promoted, advertised, marketed, distributed, and/or sold the Optetrak Devices, which were implanted in Plaintiff, such that they was dangerous, unsafe, and defective in design. The defects in the design include but are not limited to:

a. that the Optetrak Devices have propensity to undergo substantial early polyethylene wear, component loosening and/or other failure causing serious complications including tissue damage, osteolysis, and other injuries as well as the need for revision surgery in patients;

b. failure to design the packaging for the polyethylene components of the Optetrak Devices in vacuum bags that contain a secondary barrier layer containing ethylene vinyl alcohol (EVOH) as to prevent the components from undergoing increased oxidation and causing patients

to experience substantial early polyethylene wear, component loosening and/or other failure causing serious complications including tissue damage, osteolysis, and other injuries as well as the need for revision surgery;

c. that the materials used within the Optetrak Devices and packaging were of an inferior grade or quality than advertised and promoted by Defendant;

d. Defendant failed to conduct adequate testing, including wear or other testing, on components, subassemblies and/or the finished Optetrak Devices as packaged and distributed;

e. Defendant failed to test an adequate number of samples of Optetrak Devices on an ongoing basis;

f. Defendant failed to take adequate steps to specifically identify failure modes with the Optetrak Devices with clarity and to suggest methods to monitor, avoid, and/or prevent further failures;

g. Defendant failed to identify and/or note the significance of any testing that resulted in failure of the Optetrak Devices;

h. Defendant failed to take corrective actions to eliminate or minimize further failures of the Optetrak Devices;

i. Defendant failed to adequately design packaging specifications for the components, subassemblies, and/or the finished Optetrak Devices;

j. The polyethylene material used in the Optetrak Devices, in conjunction with the inferior vacuum bags, caused and/or contributed to the devices having a higher failure rate than other similar devices available at the time the Optetrak Devices were put on the market;

k. The polyethylene material used in the Optetrak Devices, in conjunction with the inferior vacuum bags, caused and/or contributed to the devices having a shorter effective lifetime than other similar devices available at the time the Optetrak Devices were put on the market;

l. The Defendant's method of manufacturing/processing the polyethylene insert and packaging was defective and increased the risk of users and patients suffering from pain, discomfort, injury and the need for revision surgery; and

m. that Defendant violated applicable state and federal laws and regulations; and in all other ways.

98. Defendant knew or reasonably should have known and been aware that the Optetrak Devices and packaging were defectively designed.

99. The design defects in the Optetrak Devices and packaging existed when the device left the Defendant's control.

100. Plaintiff's physician implanted the Optetrak Devices in the manner in which it was intended and recommended to be used, making such use reasonably foreseeable to Defendant.

101. The Optetrak Devices as tested, studied, researched, designed, formulated, manufactured, inspected, labeled, packaged, promoted, advertised, marketed, distributed, and/or sold by Defendant reached Plaintiff without substantial change in its condition.

102. As alleged herein, Defendant knew or had reason to know that the Optetrak Devices caused an increased risk of harm to the Plaintiff and other consumers due to the device's propensity to undergo substantial early polyethylene wear, component loosening, and/or other failure causing serious complications including tissue damage, osteolysis, and other injuries as well as the need for revision surgery in patients.

103. The Optetrak Devices and packaging as designed carried risks that were outweighed by any utility of the design of the device and packaging because when paired together, the Optetrak Devices were dangerous to an extent beyond that which would be contemplated by the ordinary consumer. At no time did Plaintiff have reason to believe that the Optetrak Devices and the packaging in which they were received were in a condition not suitable for proper and intended use.

104. The Optetrak Devices and packaging were defective in design and unreasonably dangerous when they entered the stream of commerce and were received by Plaintiff, because the foreseeable risks exceeded or outweighed the purported benefits associated with the device.

105. Feasible safer alternative designs providing the same functional purpose were available to the Defendant at the time the Optetrak Devices were designed and packaged and offered for sale in the market.

106. Defendant could have utilized vacuum bags containing a secondary barrier layer containing ethylene vinyl alcohol (EVOH) as to prevent the polyethylene components from undergoing increased oxidation according to its own admissions.

107. Defendant could have processed the polyethylene tibial insert to obtain high crosslinking and greater removal of free radicals. The failure to process the polyethylene to reduce the risk of early high volume polyethylene wear increased the risk of failure.

108. The design defects of the Optetrak Devices and corresponding packaging presented an unreasonable risk of harm to users and patients exposed to their danger, including Plaintiff, when used and operated for the purposes intended by Defendant.

109. The design defects of the Optetrak Devices and corresponding packaging presented an unreasonable risk of harm to users and patients exposed to their danger, including Plaintiff, when they were used and operated in a manner that was foreseeable to Defendant.

110. Plaintiff could not, by the exercise of reasonable care, have discovered these design defects and perceived its dangers or avoided injury.

111. The Defendant is strictly liable for the defective design of the Optetrak Devices; defective design of the packaging of the Device; the distribution, marketing, and/or sale of the Optetrak Device; and the injuries sustained by Plaintiff.

112. By reason of the foregoing acts, omissions and conduct committed by the Defendant, Plaintiff was caused to sustain serious personal injuries, conscious pain and suffering, physical disability, mental anguish, emotional distress, fear, loss of enjoyment of life, medical expenses, and financial losses.

113. By reason of the foregoing acts, omissions and conduct committed by Defendant, Plaintiff was caused to sustain serious personal injuries, conscious pain and suffering, and physical disability that will require continued and additional medical treatment.

114. As a direct, proximate and legal consequence of the defective nature of the Optetrak Devices as described herein, Plaintiff JACOB BRICKMAN has suffered and continues to suffer permanent and debilitating injures and damages, including but not limited to, significant pain and discomfort; gait impairment; poor balance; difficulty walking; component part loosening; soft tissue damage; bone loss; and other injuries presently undiagnosed, which all require ongoing medical care.

115. As a further direct, proximate and legal consequence of the defective nature of the Optetrak Devices, Plaintiff have sustained and will sustain future damages, including but not limited to cost of medical care; rehabilitation; home

health care; loss of earning capacity; mental and emotional distress; loss of consortium and pain and suffering.

116. Defendant acted intentionally, recklessly and wantonly without regard for Plaintiff' rights beyond all standards of decency, entitling Plaintiff to recover punitive damages.

WHEREFORE, Plaintiff demand judgment against Defendant for compensatory and punitive damages, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems proper.

THIRD CAUSE OF ACTION

STRICT LIABILITY – FAILURE TO WARN

117. Plaintiff hereby incorporates by reference the facts alleged in paragraphs 1-67 of this Complaint as if fully set forth herein and further alleges as follows:

118. Prior to Plaintiff's initial knee surgery, and at all times relevant this action, Defendant tested, studied, researched, designed, formulated, manufactured, inspected, labeled, packaged, promoted, advertised, marketed, distributed, and/or sold the Optetrak Devices for implantation into consumers, such as Plaintiff, by orthopedic surgeons in the United States.

119. Defendant had a duty to provide adequate warnings regarding the Optetrak Devices in a manner that did not present an unreasonable risk of harm or injury to users and patients exposed to their danger, including Plaintiff.

120. Defendant had a duty to distribute, market, and/or sell the Optetrak Devices with adequate warnings that did not present an unreasonable risk of harm or injury to users and patients exposed to their danger, including Plaintiff.

121. The warnings that accompanied the Optetrak Devices and corresponding packaging were defective thereby making the product not reasonably safe for its expected, intended, and/or foreseeable uses, functions and purposes.

122. The Optetrak Devices and corresponding packaging are not reasonably safe as labeled, distributed, marketed, delivered and/or sold by Defendant.

123. Inadequate labeling accompanying the Optetrak Devices and packaging received by Plaintiff's implanting surgeon proximately caused Plaintiff' injuries.

124. At all times relevant to this action, the Defendant tested, studied, researched, designed, formulated, manufactured, inspected, labeled, packaged, promoted, advertised, marketed, distributed, and/or sold the Optetrak Devices, which were implanted in Plaintiff, such that they were dangerous, unsafe, and defective.

125. The Optetrak Devices were defective and unreasonably dangerous when they entered the stream of commerce and was received by Plaintiff, because the warnings in the instructions for use, operative techniques, directions, marketing and promotional materials, advertisements, white papers, and other communications provided by Defendant or its sales force to physicians and patients with or about the Optetrak Devices failed to adequately convey the potential risks and side effects of the Optetrak Devices and their dangerous propensities, which risks were known or were reasonably scientifically knowable to Defendant.

126. In particular, Defendant failed to adequately disclose the device's propensity to undergo substantial early polyethylene wear, component loosening and/or other failure causing serious complications including tissue damage, bone loss, osteolysis, and other injuries as well as the need for revision surgery in patients. Defendant failed to warn, disclose, and/or notify surgeons, specifically Plaintiff's surgeon that the device at issue was at a greater risk of adverse local tissue damage due to its propensity to generate high volume of polyethylene wear.

127. Defendant failed to adequately warn, disclose, and/or notify surgeons, specifically Plaintiff's surgeon that the polyethylene tibial insert was at a greater risk of early high polyethylene wear than other alternative designs.

128. Defendant failed to warn, disclose, and/or notify surgeons, specifically Plaintiff's surgeon that its process of manufacturing the tibial insert created a device that was at greater risk of early high polyethylene wear.

129. Defendant consciously disregarded the increased risks of harm by failing to adequately warn of such risks; unlawfully concealing the dangerous problems associated with implantation of the Optetrak Devices; and continuing to market, promote, sell and defend the Optetrak Devices until the very recent recall.

130. Defendant knew or reasonably should have known and been aware that the Optetrak Devices and packaging contained inadequate warnings.

131. The inadequate warnings for the Optetrak Devices existed when the devices left the Defendant's control.

132. Plaintiff's physician implanted the Optetrak Devices in the manner intended and recommended to be used, making such use reasonably foreseeable to Defendant.

133. The Optetrak Devices as tested, studied, researched, designed, formulated, manufactured, inspected, labeled, packaged, promoted, advertised, marketed, distributed, and/or sold by Defendant reached Plaintiff without substantial change in its condition.

134. As alleged herein, Defendant knew or had reason to know that the Optetrak Devices caused an increased risk of harm to the Plaintiff and other consumers due to their propensity to generate early high volume polyethylene wear, component loosening, and/or other failure causing serious complications including tissue damage, osteolysis, and other injuries as well as the need for revision surgery in patients.

135. The Optetrak Devices that were labeled, manufactured, distributed, and sold by the Defendant to Plaintiff were in a defective condition that was unreasonably dangerous to any user or ordinary consumer of the device, including Plaintiff.

136. The labeling defects of the Optetrak Devices and corresponding packaging presented an unreasonable risk of harm to users and patients exposed to its danger, including Plaintiff, when the Devices were used and operated for the purposes intended by Defendant.

137. The labeling defects of the Optetrak Devices and corresponding packaging presented an unreasonable risk of harm to users and patients exposed to their danger, including Plaintiff, when they were used and operated in a manner that was foreseeable to Defendant.

138. Plaintiff could not, by the exercise of reasonable care, have discovered these defects and perceived its dangers or avoided injury.

139. Defendant failed to issue new warnings or initiate a recall in a timely manner as to help minimize the damage and bone loss occurring in patients, including Plaintiff.

140. The Defendant is strictly liable for providing inadequate warnings accompanying the Optetrak Devices and packaging of the Devices; the distribution, marketing, and/or sale of the Optetrak Devices; and the injuries sustained by Plaintiff.

141. By reason of the foregoing acts, omissions and conduct committed by the Defendant, Plaintiff was caused to sustain serious personal injuries, conscious pain and suffering, physical disability, mental anguish, emotional distress, fear, loss of enjoyment of life, medical expenses, and financial losses.

142. By reason of the foregoing acts, omissions and conduct committed by Defendant, Plaintiff was caused to sustain serious personal injuries, conscious pain and suffering, and physical disability that will require continued and additional medical treatment.

143. As a direct, proximate and legal consequence of the defective nature of the Optetrak Devices as described herein, Plaintiff JACOB BRICKMAN has suffered and continues to suffer permanent and debilitating injures and damages, including but not limited to, significant pain and discomfort; gait impairment; poor balance; difficulty walking; component part loosening; soft tissue damage; bone loss; and other injuries presently undiagnosed, which all require ongoing medical care.

144. As a further direct, proximate and legal consequence of the defective nature of the Optetrak Devices, Plaintiff have sustained and will sustain future damages, including but not limited to cost of medical care; rehabilitation; home health care; loss of earning capacity; mental and emotional distress; loss of consortium and pain and suffering.

145. Defendant acted intentionally, recklessly and wantonly without regard for Plaintiff' rights beyond all standards of decency, entitling Plaintiff to recover punitive damages.

146. WHEREFORE, Plaintiff demand judgment against Defendant for compensatory and punitive damages, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems proper.

FOURTH CAUSE OF ACTION

NEGLIGENCE

147. Plaintiff hereby incorporates by reference the facts alleged in paragraphs 1-67 of this Complaint as if fully set forth herein and further alleges as follows:

148. Prior to Plaintiff's initial knee implants, and at all times relevant this action, Defendant tested, studied, researched, designed, formulated, manufactured, inspected, labeled, packaged, promoted, advertised, marketed, distributed, and/or sold the Optetrak Devices for implantation into consumers, such as Plaintiff, by orthopedic surgeons in the United States.

149. Prior to, on, and after the dates of Plaintiff's initial knee surgeries, and at all times relevant to this action, Defendant had a duty to exercise reasonable care in testing, study, research, design, formulation, manufacture, inspection, labeling, packaging, promotion, advertisement, marketing, distribution and sale of the Optetrak Devices for implantation into consumers, such as Plaintiff, by physicians and surgeons in the United States.

150. Prior to, on, and after the dates of Plaintiff's initial knee surgery, Defendant breached this duty and failed to exercise reasonable care and were grossly

negligent and careless in the testing, study, research, design, formulation, manufacture, inspection, labeling, packaging, promotion, advertisement, marketing, distribution and sale of the Optetrak Devices.

151. Following Plaintiff's initial knee surgery, Defendant breached this duty and failed to exercise reasonable care and were grossly negligent and careless in failing to recall the Optetrak Devices.

152. At all times material hereto, the Defendant had actual knowledge, or in the alternative, should have known through the exercise of reasonable and prudent care, of the hazards and dangers associated with the Optetrak Devices.

153. Defendant had access to registry data and were aware of complaints that the Optetrak Devices caused serious complications including but not limited to polyethylene wear and/or other failure causing serious complications including component loosening, tissue damage, osteolysis, bone loss and the need for revision surgery in patients.

154. Despite the fact Defendant knew or should have known the Optetrak Devices posed a serious risk of bodily harm to consumers, Defendant continued to manufacture and market the Optetrak Device for implantation into consumers.

155. Despite the fact Defendant knew or should have known the Optetrak Devices posed a serious risk of bodily harm to consumers, Defendant continued to manufacture and market the Optetrak Devices for implantation into consumers without revising any warning language or issuing an earlier recall.

156. Defendant failed to advise surgeons and patients of the need for regular follow up beyond the ordinary practices after a total knee implant as to promptly detect polyethylene degradation and osteolytic failure and timely revise the device to prevent or at least minimize bone loss, osteolysis and related injuries.

157. Defendant failed to exercise due care under the circumstances, and its negligence and recklessness includes the following acts and omissions:

a. Negligently failing to properly package the polyethylene components of the Optetrak Devices;

b. Negligently failing to select appropriate third-parties to package the polyethylene inserts used in the Optetrak Devices;

c. Negligently failing to properly supervise and monitor the packaging of the polyethylene inserts used in the Optetrak Devices;

d. Negligently failing to properly and thoroughly select the material that would be used in the packaging of the Optetrak Devices;

e. Negligently failing to properly process/manufacture the materials that would be used in the Optetrak Devices;

f. Negligently failing to properly and adequately test the Optetrak Devices and its attendant parts before releasing the devices to market;

g. Negligently failing to conduct sufficient post-market testing and surveillance of the Optetrak Devices;

h. Negligently failing to adequately prevent, identify, mitigate, and fix defective designs and hazards associated with the Optetrak Devices in accordance with good practices;

i. Negligently designing, manufacturing, marketing, advertising, distributing, and selling the Optetrak Devices;

j. Continuing to negligently manufacture, and distribute the Optetrak Devices after the Defendant knew or should have known of their adverse effects and/or the increased early onset failure rates;

k. Negligently designing, manufacturing, marketing, advertising, distributing, and selling the Optetrak Devices to consumers, including Plaintiff, without an adequate warning of the dangerous risks of the Optetrak Devices;

l. Negligently failing to notify and warn the public, including Plaintiff, and physicians of reported incidents involving injury and the negative health effects attendant to the use of the Optetrak Devices;

m. Negligently misrepresenting the safety of the Optetrak Devices;

n. Negligently failing to provide warnings, instructions or other information that accurately reflected the risks of failure of the Optetrak Devices;

o. Negligently failing to provide warnings, instructions or other information that accurately reflected the risks of early degradation of the polyethylene substance in the Optetrak Devices;

p. Negligently failing to exercise due care in the advertisement and promotion of the Optetrak Devices;

q. Negligently disseminating information that was inaccurate, false, and misleading, and which failed to communicate accurately or adequately the high early failure rate associated with the implantation of the Optetrak Devices;

r. Aggressively promoting the Optetrak Devices without proper warnings of the risk of early failure or material degradation in the average user;

s. Aggressively promoting the Optetrak Devices even after Defendant knew or should have known of the unreasonable risks from implantation;

t. Negligently failing to warn consumers, doctors, users and patients that the Optetrak Devices would contain polyethylene materials not properly packaged and/or in accordance with Defendant's specifications;

u. Negligently diminishing or hiding the risks associated with the implantation of the Optetrak Devices;

v. Negligently failing to recall the Optetrak Devices at an earlier date and institute a process to have patients notified;

w. Negligently failing to inform surgeons within a reasonable time of the recall of the Optetrak Devices;

x. Negligently violating applicable state and federal laws and regulations; and in all other ways.

158. Defendant knew and/or should have known that it was foreseeable that consumers such as Plaintiff would suffer injuries as a result of Defendant's failure to exercise ordinary care in the manufacture, design, testing, assembly, inspection, labeling, packaging, supplying, marketing, selling, advertising, preparing for use, warning of the risks and dangers of the defective implants, and otherwise distributing the Optetrak Devices.

159. By reason of the foregoing acts, omissions and conduct committed by the Defendant, Plaintiff was caused to sustain serious personal injuries, conscious pain and suffering, physical disability, mental anguish, emotional distress, fear, loss of enjoyment of life, medical expenses, and financial losses.

160. By reason of the foregoing acts, omissions and conduct committed by Defendant, Plaintiff was caused to sustain serious personal injuries, conscious pain and suffering, and physical disability that will require continued and additional medical treatment.

161. As a direct and proximate result of Defendant's acts and omissions, including its failure to exercise ordinary care in the design, formulation, testing, manufacture, labeling, sale, and distribution of the Optetrak Devices, Plaintiff JACOB BRICKMAN was implanted with the Optetrak Device and was caused to

sustain serious personal injuries, conscious pain and suffering, physical disability, mental anguish, emotional distress, fear, loss of enjoyment of life, medical expenses, and financial losses.

162. As a further direct, proximate and legal consequence of Defendant's acts and omissions, including its failure to exercise ordinary care in the design, formulation, testing, manufacture, labeling, sale, and distribution of the Optetrak Devices, Plaintiff have sustained and will sustain future damages, including but not limited to cost of medical care; rehabilitation; home health care; loss of earning capacity; mental and emotional distress; loss of consortium and pain and suffering.

163. Defendant acted intentionally, recklessly and wantonly without regard for Plaintiff' rights beyond all standards of decency, entitling Plaintiff to recover punitive damages.

WHEREFORE, Plaintiff demand judgment against Defendant for compensatory and punitive damages, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems proper.

FIFTH CAUSE OF ACTION

NEGLIGENT MISREPRESENTATION

164. Plaintiff hereby incorporates by reference the facts alleged in paragraphs 1-67 of this Complaint as if fully set forth herein and further alleges as follows:

165. Prior to Plaintiff's initial knee surgeries, and at all times relevant this action, Defendant tested, studied, researched, designed, formulated, manufactured, inspected, labeled, packaged, promoted, advertised, marketed, distributed, and/or sold the Optetrak Devices for implantation into consumers, such as Plaintiff, by orthopedic surgeons in the United States.

166. Defendant owed a duty to orthopedic surgeons, other healthcare providers, and consumers of the Optetrak Devices, including Plaintiff, to accurately and truthfully represent the risks of the Optetrak Devices. Defendant breached its duty by misrepresenting and/or failing to warn Plaintiff's orthopedic surgeon, the medical community, Plaintiff, and the public about the risks of the Optetrak Devices, including their propensity to generate early high volume polyethylene wear, debris, component loosening and/or other failure causing serious complications including tissue damage, osteolysis, and other injuries as well as the need for revision surgery in patients, which Defendant knew or in the exercise of diligence should have known.

167. The Defendant, as the designer, manufacturer, seller, promoter, and/or distributor of the Optetrak Devices knew, or reasonably should have known, that health care professionals and consumers of the Optetrak Devices would rely on information disseminated and marketed to them regarding the product when weighing the potential benefits and potential risks of implanting Optetrak Devices.

168. The Defendant, as the designer, manufacturer, seller, promoter, and/or distributor of the Optetrak Devices knew, or reasonably should have known, that the patients implanted with Optetrak Devices would suffer early failure and require revision surgery because the information disseminated by Defendant and relied upon by health care professionals and consumers, including Plaintiff, was materially inaccurate, misleading, or otherwise false.

169. The Defendant failed to exercise reasonable care to ensure that the information they disseminated to health care professionals and consumers concerning the quality and longevity of the Optetrak Devices was accurate, complete, and not misleading. As a result, Defendant disseminated information to health care professionals and consumers that was materially inaccurate, misleading, false, and unreasonably dangerous to consumers such as Plaintiff.

170. Among Defendant's numerous misrepresentations and misleading omissions are Defendant's assurances that the Optetrak Devices were safe, had an excellent performance record, and was at low risk for high volume polyethylene wear debris, component loosening and/or other failure causing serious complications including tissue damage, osteolysis and other injuries as well as the need for revision surgery in patients.

171. Despite its knowledge of serious problems with the Optetrak Devices, Defendant urged its sales representatives to continue marketing the Optetrak Devices, and distributed medical literature, white papers, non-peer reviewed studies, and other communications to surgeons in an effort to mislead them and the general public about the risks associated with the Optetrak Devices and instead create the image and impression that the Optetrak Devices were safe.

172. Defendant made such statements even after they became aware of numerous and serious complications with the Optetrak Devices. Defendant did not reveal (and instead concealed) its knowledge of numerous and serious complications and other bad data.

173. Defendant made these representations with the intent to induce reliance thereon, and to encourage purchase and implantation of the Optetrak Device.

174. The misrepresentations made by Defendant, in fact were false and known by Defendant to be false at the time the misrepresentations were made and were made prior to Plaintiff's index surgeries in 2011.

175. Misrepresentations spanned a number of years, but also include the critical time period of 2017 – 2018 when the company was in the process of being acquired by the Private Equity Group TPG Capital which in February 2018 successfully completed a merger agreement. As a result, TPG acquired all of the issued and outstanding common stock of Exactech. In connection with the transaction, Exactech's founders, CEO and certain other management shareholders exchanged a portion of their shares in the transaction, for new equity securities in the post-closing ownership of the Company. *See Exactech Announces Completion of Merger with TPG Capital* (Feb. 14, 2018) *available at* https://www.exac.com/exactech-announces-completion-of-merger-with-tpg-capital/ (last visited June 6, 2022).

176. Full disclosure of the magnitude of the problem with the polyethylene failure might have negatively impacted the merger prospects and the merger may have been one of the reasons the problems were concealed. Nevertheless, after the merger in 2018, it still took four years for Defendant to reveal the product defects

and their health consequences to the medical community and to the patients, including Plaintiff, even though the key officers of Exactech generally continued with their roles in the newly merged company.

177. Defendant failed to exercise ordinary care in making its representations concerning the Optetrak Devices and, in the manufacture, sale, testing, quality assurance, quality control, and distribution in interstate commerce of the Optetrak Devices.

178. Defendant's misrepresentations were knowingly made to Plaintiff's surgeon, relied upon by him, and proximately caused Plaintiff's injuries.

179. By reason of the foregoing acts, omissions and conduct committed by the Defendant, Plaintiff was caused to sustain serious personal injuries, conscious pain and suffering, physical disability, mental anguish, emotional distress, fear, loss of enjoyment of life, medical expenses, and financial losses.

180. By reason of the foregoing acts, omissions and conduct committed by Defendant, Plaintiff was caused to sustain serious personal injuries, conscious pain and suffering, and physical disability that will require continued and additional medical treatment.

181. As a direct and proximate result of Defendant's acts and omissions, including Defendant's negligent misrepresentations regarding the Optetrak Devices, Plaintiff JACOB BRICKMAN was implanted with the Optetrak Device in both knees, and was caused to sustain serious personal injuries, conscious pain and suffering, physical disability, mental anguish, emotional distress, fear, loss of enjoyment of life, medical expenses, and financial losses.

182. As a further direct, proximate and legal consequence of Defendant's acts and omissions, including Defendant's negligent misrepresentations regarding the Optetrak Devices, Plaintiff have sustained and will sustain future damages, including but not limited to cost of medical care; rehabilitation; home health care; loss of earning capacity; mental and emotional distress; loss of consortium and pain and suffering.

183. Defendant acted intentionally, recklessly and wantonly without regard for Plaintiff' rights beyond all standards of decency, entitling Plaintiff to recover punitive damages.

WHEREFORE, Plaintiff demands judgment against Defendant for compensatory and punitive damages, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems proper.

SIXTH CAUSE OF ACTION

BREACH OF EXPRESS WARRANTY

184. Plaintiff hereby incorporates by reference the facts alleged in paragraphs 1-67 of this Complaint as if fully set forth herein and further allege as follows:

185. Prior to Plaintiff's initial knee surgeries, and at all times relevant this action, Defendant tested, studied, researched, designed, formulated, manufactured, inspected, labeled, packaged, promoted, advertised, marketed, distributed, and/or sold the Optetrak Devices for implantation into consumers, such as Plaintiff, by orthopedic surgeons in the United States.

186. Defendant expressly warranted the Optetrak Devices, including the Optetrak Comprehensive Total Knee System and/or the Optetrak Logic Comprehensive Knee System, were safe and effective orthopedic devices.

187. Defendant promised that the Optetrak Devices had excellent long-term clinical outcomes and that "surgeons and patients can have every confidence in the performance and longevity of the Optetrak knee system."

188. At the time Defendant manufactured, marketed, sold and/or distributed the Optetrak Devices, they knew that the devices were intended for human use, and that Plaintiff was a foreseeable user of the Optetrak Devices.

189. The express warranties represented by Defendant were a part of the basis for Plaintiff's use of the Optetrak Devices, and he and his surgeon relied on these warranties in deciding to use the Optetrak Device.

190. At the time of the making of the express warranties, Defendant had knowledge of the purpose for which the Optetrak Devices were to be used and warrantied the same to be in all respects safe, effective and proper for such purpose.

191. The Optetrak Devices do not conform to these express representations as demonstrated by the fact that Plaintiff's implant failed prematurely due to reasons related to the recall and defects with the device and he is scheduled to undergo revision surgery.

192. At the time Defendant marketed, sold and/or distributed the Optetrak Devices, Defendant expressly warranted that the total knee replacement systems, including all of their component parts, were safe and merchantable for their intended use.

193. Plaintiff JACOB BRICKMAN and his implanting physician reasonably relied upon Defendant's express warranties.

194. Plaintiff JACOB BRICKMAN used the Optetrak Device for its intended purpose, and in a reasonable foreseeable manner.

195. The Optetrak Devices manufactured and sold by Defendant, did not conform to Defendant's express representations because the Optetrak Devices caused serious injury to Plaintiff when used as recommended and directed.

196. As a direct and proximate result of Defendant's acts and omissions, including breach of express warranty, Plaintiff JACOB BRICKMAN was implanted in both knees with an Optetrak Device and was caused to sustain serious personal injuries, conscious pain and suffering, physical disability, mental anguish, emotional distress, fear, loss of enjoyment of life, medical expenses, and financial losses.

197. As a further direct, proximate and legal consequence of Defendant's acts and omissions, including breach of express warranty, Plaintiff have sustained and will sustain future damages, including but not limited to cost of medical care; rehabilitation; home health care; loss of earning capacity; mental and emotional distress; loss of consortium and pain and suffering.

WHEREFORE, Plaintiff demand judgment against Defendant for compensatory damages, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems proper.

SEVENTH CAUSE OF ACTION

BREACH OF IMPLIED WARRANTY

198. Plaintiff hereby incorporates by reference the facts alleged paragraphs 1-67 of this Complaint as if fully set forth herein and further alleges as follows:

199. Prior to Plaintiff's initial knee surgery, and at all times relevant this action, Defendant tested, studied, researched, designed, formulated, manufactured, inspected, labeled, packaged, promoted, advertised, marketed, distributed, and/or sold the Optetrak Devices for implantation into consumers, such as Plaintiff, by orthopedic surgeons in the United States.

200. Defendant impliedly warranted, through its marketing, advertising, distributors and sales representatives, that the Optetrak Devices were of merchantable quality, and fit for the ordinary purposes and uses for which it was sold.

201. In fact, the Optetrak Devices were not of merchantable quality nor fit for the ordinary purposes and uses for which they were sold and did not meet the

expectations of consumers. The Optetrak Devices manufactured and supplied by Defendant was not of merchantable quality and was not fit for the ordinary and/or particular purpose for which it was intended as physicians and patients would expect the components to be properly packaged and stored as to avoid premature degradation of component materials.

202. Plaintiff JACOB BRICKMAN and/or his physician reasonably relied upon the skill and judgment of Defendant as to whether the Optetrak Devices were of merchantable quality and safe for its intended and particular use and purpose.

203. Contrary to such implied warranties, the Optetrak Devices were not of merchantable quality or safe for their intended and particular uses and purposes, because Defendant failed to package the polyethylene components of the Optetrak Devices in vacuum bags containing a secondary barrier layer containing ethylene vinyl alcohol (EVOH) as to prevent the components from undergoing increased oxidation and causing patients to experience substantial early polyethylene wear, component loosening and/or other failure causing serious complications including tissue damage, osteolysis, and other injuries as well as the need for revision surgery.

204. As a direct and proximate result of Defendant's acts and omissions, including breach of implied warranties, Plaintiff JACOB BRICKMAN was

implanted with an Optetrak Device in each knee and was caused to sustain serious personal injuries, conscious pain and suffering, physical disability, mental anguish, emotional distress, fear, loss of enjoyment of life, medical expenses, and financial losses.

205. As a further direct, proximate and legal consequence of Defendant's acts and omissions, including breach of implied warranties, Plaintiff has sustained and will sustain future damages, including but not limited to cost of medical care; rehabilitation; home health care; loss of earning capacity; mental and emotional distress; loss of consortium and pain and suffering.

WHEREFORE, Plaintiff demands judgment against Defendant for compensatory damages, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems proper.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff demands judgment against Defendant as follows:

a. Judgment in favor of Plaintiff and against Defendant, for damages in such amounts as may be proven at trial;

b. Compensation for both economic and non-economic losses, including but not limited to medical expenses, loss of earnings, loss of consortium,

disfigurement, pain and suffering, mental anguish, and emotional distress, in such amounts as may be proven at trial;

c. Punitive and/or exemplary damages in such amounts as may be proven at trial;

d. Attorneys' fees and costs;

e. Interest; and

f. Any and all further relief, both legal and equitable, that the Court may deem just and proper.

JURY TRIAL DEMANDED.

DATED: June 14, 2022

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